

November 22, 1978

Cas. No. 188 AAA

Meeting with the Registrant (Rohm and Haas) Regarding a 20-Month Mouse Feeding Study with RH-2915 (Goal^R Technical) and Perchloroethylene Carcinogenic Risk Assessment.

Lamar B. Dale Jr., Ph.D.

Acting Chief, Toxicology Branch/HED (TS-769)

Robert Taylor

Product Manager #25, Registration Division (TS-767)

Persons in Attendance:

- Dr. P. Newberne (MIT)
- Dr. S. Kresminski (Rohm and Haas)
- Dr. J. Smith (Rohm and Haas)
- Dr. W. Dykstra (Toxicology Branch)
- Dr. S. L. Chan (Toxicology Branch)
- Dr. L. B. Dale (Acting Chief, Toxicology Branch)
- Robert Taylor (Product Manager #25)
- Dr. L. Mishra (Toxicology Branch)
- Roger Gardner (Toxicology Branch)

The meeting convened at 10:30 a.m. in the third floor conference room, East Tower, Waterside Mall.

Dr. Kresminski (Rohm and Haas) discussed the cancer risk associated with the [redacted] residue of perchloroethylene (PCE, a solvent used in the manufacture of technical grade Goal^R). He mentioned the Agency's acceptance of the levels of PCE found in formulations as permissible (Code of Federal Regulations 40, Section 180.1001, page 391).

A letter from Dr. Newberne (MIT) to Dr. Smith (Rohm and Haas) was presented as background information for subsequent discussions (See attachment.).

Dr. Newberne explained the microscopic responses observed in livers from mice given a variety of chemicals from enzyme inducers such as phenobarbital to carcinogens such as AAF. He explained the hyperplastic nodules observed in the mice treated with Goal^R were the result of focal necrosis followed by tissue regeneration. He further stated that hyperplastic nodules are reversible in animals younger than those examined in the Goal^R study when administration of a toxic substance is stopped. Also, he described two criteria used to identify malignant tumors, and these are (1) infiltration or invasion of surrounding tissue by tumor cells, and (2) metastasis to other organs such as the lung. He found no compound related incidence of such tumors in the slides he examined.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Because of the considerations described above, Dr. Newberne and the Toxicology Branch views the hyperplastic nodules as regeneration of liver damage associated with the toxicity of Goal^R. It was concluded by the Toxicology Branch that the 20-month study with mice showed no carcinogenic activity associated with Goal^R.

Attachment

cc: William Dykstra, Ph.D.
Toxicology Branch/HED

S.L. Chan, Ph.D. ✓
Acting Section Head #5,
Toxicology Branch/HED.